

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ENDO PHARMACEUTICALS INC.,

Case No. 13-cv-3288-TPG-GWG

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

**REPLY BRIEF OF ROXANE LABORATORIES, INC. IN SUPPORT OF  
ITS MOTION FOR LEAVE TO FILE A FIRST AMENDED ANSWER**

**INTRODUCTION**

Endo's opposition brief does not dispute the liberal standards for amendment under the federal rules. It does not dispute Roxane's good faith or the absence of prejudice. And it does not substantively dispute the issue of delay.\* Instead, the opposition rests solely on Endo's futility argument regarding the defenses of express and implied license. Endo says amendment is futile because the Federal Circuit decided these issues against Roxane in its preliminary-injunction opinion and that ruling is binding law of the case.

Accordingly, the only issue left for the Court to decide is whether the Federal Circuit's ruling on preliminary injunction precludes further development of the issues of express and implied license going forward on the merits.

For its part, Endo leans heavily on a 1961 Second Circuit decision, *Lummus Co. v. Commonwealth Oil Refining Co.*, 297 F.2d 80 (2d Cir. 1961), which Endo says permits treating

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\* Endo also consents to Roxane's amending of its answer to assert a defense of unclean hands. Thus, no matter how the Court rules on the license defenses, an order should issue granting Roxane leave to file an amended answer with an unclean-hands defense.

preliminary-injunction findings as final and binding. Ascribing such a broad general holding to *Lummus* would, however, conflict with the Supreme Court's later decision in *University of Texas v. Camenisch*, 451 U.S. 390 (1981), and with the Federal Circuit's decisions in *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679 (Fed. Cir. 1990), and *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), all of which unequivocally hold that findings of fact and even appellate court opinions on a preliminary injunction are not binding at a subsequent trial on the merits. These courts correctly reason that preliminary injunctions are typically decided in hurried and abbreviated proceedings on less than a full record and are reviewed only for an abuse of the district court's discretion. Therefore, the parties should be permitted to develop further facts at a more contemplative trial.

In fact, Endo neglects to inform the Court that *Lummus* represents a *narrow exception* to the general rule that findings on a preliminary injunction are not binding going forward on the merits. *See, e.g., Goodheart Clothing Co., Inc. v. Laura Goodman Enters., Inc.*, 962 F.2d 268, 274 (2d Cir. 1992) (noting that “[i]t would . . . be anomalous at least in most cases, and here, to regard the initial ruling as foreclosing the subsequent, more thorough consideration of the merits that the preliminary injunction expressly envisions”); *Don King Productions, Inc. v. Douglas*, 742 F. Supp. 741, 754 (S.D.N.Y. 1990) (noting that findings made in a preliminary-injunction proceeding are “seldom considered sufficiently final to be given preclusive effect”); *Rivera v. Mattingly*, No. 06 Civ. 7077 TPG, 2011 WL 4344422, at \*6-7 (S.D.N.Y. Sept. 12, 2011) (holding that court's statements made in conjunction with preliminary injunction were not subject to the law-of-the-case doctrine and did not foreclose a more thorough consideration of the merits). This narrow exception applies only when the hearing on preliminary injunction has been so thorough and so complete, with the parties given such a full chance to present all their

crucial witnesses and evidence, that the ensuing ruling must be considered practically final. *See Goodheart Clothing Co., Inc.*, 962 F.2d at 274.

That cannot be said about the preliminary-injunction hearing here—by a long stretch. Here the parties presented no witnesses at the hurriedly scheduled preliminary-injunction hearing, and only Endo submitted evidence about the contract negotiations leading up to the 2011 settlement and license agreement. Endo submitted that evidence, not in its opening brief to provide Roxane with an opportunity to respond, but in its reply brief, which it filed less than 48 hours before the preliminary-injunction hearing. Moreover, the Federal Circuit, in reversing, relied only on Endo’s evidence of the contract negotiations (which had not been subject to cross examination) because Roxane’s countervailing evidence was not yet in the record. In fact, this Court noted that it did not have an appropriate record to render a final decision as to the license negotiation issues. In these circumstances, this Court should not treat the Federal Circuit’s preliminary-injunction findings as “practically final” such as to preclude all future consideration of the license issues.

### **ADDITIONAL BACKGROUND**

As the Court will recall, Endo filed its motion for preliminary injunction on August 6, 2013. Endo’s brief in support of its preliminary-injunction motion did not address Roxane’s license defenses and did not present any license negotiation evidence. Before Roxane responded, the Court held a hearing on August 26 at which the Court suggested, and the parties agreed, to limit the preliminary-injunction hearing for the time being to Roxane’s and Actavis’s license defenses. Roxane thus filed its brief in opposition to the preliminary injunction on September 3, asserting both express and implied licenses. In that brief, Roxane argued that the license terms were unambiguous.

Endo filed its reply brief on September 10, 2013. This brief for the first time discussed the negotiations leading up to the 2011 settlement and license agreement. Endo attached to this reply brief the declaration of Guy Donatiello, Endo's vice president for intellectual property, detailing Donatiello's one-sided view of the negotiations for the settlement and license agreement and Endo's supposed intent in entering that agreement.

At the request of Actavis, which was getting ready to launch its generic product, the Court held a preliminary-injunction hearing almost immediately after briefing finished, on September 12. Donatiello was present at the hearing, but Roxane's representative from the contract negotiations, David Dow, was out of the country and unavailable to respond to Donatiello's declaration, which had been served just two days before the hearing. The Court did not take any live testimony at the hearing. Thus, there was never any opportunity to cross-examine Donatiello about the statements in his declaration. The Court also did not rely on Endo's documentary evidence of the parties' negotiations. Instead, the Court followed *TransCore, LP v. Elec. Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), to hold that Roxane had an implied license in the asserted patent claims. (Ex. 3<sup>†</sup> at pg. 49, Ins. 6-25.)

In reversing, the Federal Circuit reached the issue of express license—an issue this Court did not decide—and relied on Donatiello's declaration (which had not been subject to cross-examination) in holding that the license did not cover the patents asserted in this lawsuit. *Endo Pharm. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1375 (Fed. Cir. 2014).

After the appeal was initiated, discovery in this case proceeded. In February 2014, Roxane cross-examined Donatiello at deposition and produced Donatiello's negotiating

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<sup>†</sup> "Ex. \_\_" refers to the corresponding exhibits to the Declaration of Myoka K. Goodin in Support of Reply Brief in Support of Roxane's Motion for Leave to File a First Amended Answer.

counterpart from Roxane, David Dow, for his own deposition. These depositions yielded testimony that called into serious question the veracity of the averments in Donatiello's declaration (which the Federal Circuit had relied on in its decision). From this more recent deposition testimony, a trier of fact could well conclude that Roxane intended to secure, and believed it had secured, an express license in the subject matter claimed in the '122 and '216 patents sufficient to enable Roxane to bring to market its ANDA product on the original Opana ER formulation without infringing on any of Endo's rights in those patents.

Of course, none of this later-adduced evidence was before this Court or in the appeal record that the Federal Circuit considered.

### **ARGUMENT**

Based on the above, the Court should conclude that there has not been a sufficiently complete hearing on the license issues that were before the Federal Circuit so as to render the Federal Circuit's decision "final" in the *Lummus* sense and therefore preclusive.

The case law, including authority that Endo cites, teaches what constitutes the type of complete and comprehensive hearing that can give rise to a preliminary-injunction ruling that is preclusive going forward. For example, in *AM General Corp. v. DaimlerChrysler Corp.*, 246 F. Supp. 2d 1030 (N.D. Ind. 2003), the preliminary-injunction hearing spanned eight days and coincided with a summary-judgment ruling. Similarly, in *Amalgamated Sugar Co. v. NL Industries, Inc.*, 667 F. Supp. 87, 94 (S.D.N.Y. 1987), "counsel on both sides exhausted their coffers" and the "opinion was predicated upon a careful analysis of all the information that very competent counsel on both sides over a period of weeks" had laid out to the court. Along these same lines, Judge Sweet has observed that "on occasion" estoppel has been found on preliminary-injunction findings "made after extensive hearing and briefing consolidated with

trial on the merits.” *Don King Prods., Inc. v. Douglas*, 742 F. Supp. at 754 (citing *Commodity Futures Trading Comm. v. Board of Trade*, 701 F.2d 653, 657–58 (7th Cir. 1983), where circumstances made it likely that preliminary-injunction findings were accurate and reliable after a consolidated six-day hearing.).

The proceedings in the case at bar were nowhere near the magnitude of the proceedings in the preliminary-injunction cases where rulings have been deemed preclusive or binding. In fact, during the September 12 preliminary-injunction hearing, this Court acknowledged that the parties held differing views on the scope of and intent behind the 2011 settlement and license agreement: “Endo claims that...there was no intent to license or give any permission to market products or seek permission of anything that would infringe [the] ‘122 and ‘216 [patents]” and on the other hand “[Roxane] claims that...there was no intent to project any possibility of litigating infringement about the ‘122 and ‘216, and...the licenses and permissions are broad enough to cover [the] ‘122 and ‘216 [patents].” (Ex. 3 at pg. 47, ln. 20-pg. 48, ln. 5.) The Court stated that “I do not feel, for purposes of a preliminary injunction motion, that I am able to make any findings on the issues that I have just described, and I want to make it clear that that’s exactly where I stand....[A] much more substantial hearing and, indeed, a full trial would be necessary to fully explore what is involved in the issues.” (*Id.* at pg. 48, lns. 6-18.)

The Court’s comments were well-founded, as there are several reasons why the proceedings to date have been insufficiently complete to invoke preclusion. First and foremost, the Federal Circuit considered only Endo’s evidence of contract negotiations—in the form of Donatiello’s declaration—because that was the only evidence in the record at the time. *Endo Pharm. Inc.*, 746 F.3d at 1375. Not only was it unfair to rely on only one party’s evidence, but that alone should preclude the Court from viewing the Federal Circuit’s opinion as binding

because it did not reflect a full airing of all the evidence. After all, Donatiello's declaration had not been subject to cross-examination and Roxane had no opportunity to present countervailing evidence. It was bad enough that the Federal Circuit relied on such incomplete and one-sided evidence in its preliminary-injunction ruling—but it would create serious due-process problems if that ruling were held to be preclusive of the license issues in the case for all time.

Further, unlike in the cases holding preliminary-injunction findings preclusive, there has never been any proceeding tantamount to a trial on the merits on the express- or the implied-license issues. This Court held a short preliminary-injunction hearing at which no witnesses testified, and the Federal Circuit's decision was based on the abbreviated record developed in connection with that hearing. As this Court recognized, that hearing did not purport to fully and finally resolve the question of whether an express or an implied license precluded Endo from asserting the patent claims in suit against Roxane. (Ex. 3 at pg. 48, lns. 6-18.)

Endo should not be heard to argue that the negotiation history was irrelevant to the Federal Circuit's decision. Such a contention is unsustainable given the appeals court's express reliance on contract language that "Endo and Roxane considered including in their agreement" but "does not appear in the final version of the Roxane Agreement." *Endo Pharm. Inc.*, 746 F.3d at 1375. This analysis makes crystal clear that the appeals court considered Endo's version of the parties' negotiations (which Roxane had objected to as parol evidence and hearsay). The appeals court, however, did not consider Roxane's evidence on the negotiations because it had not yet been produced. This incomplete review of only one party's evidence, which had never even been subject to cross examination, does not constitute the type of complete hearing that would lead to a finding of finality even if *Lummus* is the governing law here.

Moreover, the Federal Circuit's view of the express-license agreement appeared to determine its resolution of the implied-license issue as well, at least as to Roxane. *Endo Pharm. Inc.*, 746 F.3d at 1376. Thus, the appeals court's review of an incomplete record infected both the express- and implied-license issues on the appeal. *Id.* This Court has the right and the duty to pass on both of these issues based on a full record and a thorough hearing.

Endo seeks to gain some advantage from Roxane's previous argument that the 2011 settlement and license agreement is unambiguous and thus evidence of negotiations is irrelevant. The Federal Circuit, however, did not treat these negotiations as irrelevant. To be sure, in one breath the court said that the contract language is "clear on its face," but in the next breath the court referred to and cited, to "reinforce" its conclusion, Donatiello's declaration setting forth Endo's view of the parties' intent leading up to the agreement's execution. *Id.* at 1375. Roxane does not believe the settlement agreement is ambiguous; it believes the agreement is unambiguous in Roxane's favor. Nevertheless, if there is deemed to be an ambiguity, the Court should have the benefit of *both parties'* evidence of the negotiating history. As this Court noted, "a full trial would be necessary to fully explore" that issue. (*See* Ex. 3 at pg. 48, Ins. 12-18.) Because the Federal Circuit did not have all the evidence before it, its decision was not final and is subject to revision.

Finally, Endo's concerns about "sandbagging" are misplaced. Roxane has no need to introduce into this reply brief the new evidence that it has obtained from the Donatiello and Dow depositions because this brief merely supports Roxane's request to amend its answer to assert defenses that this testimony supports. The only remaining question on leave to amend is the preclusive effect of the Federal Circuit's ruling, and Roxane has demonstrated that this is not one of those rare and exceptional cases where a preliminary-injunction ruling was so thorough and



based on such a complete hearing that it should be preclusive on the issue at trial. Indeed, if anyone is guilty of sandbagging here, it is Endo, which first attached Donatiello's declaration to its own reply brief in support of its motion for preliminary injunction, two days before the preliminary-injunction hearing and now seeks to foreclose further evidence and consideration of the license issues.

### **CONCLUSION**

For these reasons, the Court should grant Roxane leave to amend its answer to assert these additional affirmative defenses.

Dated: July 21, 2014

By: /s/ Alan B. Clement

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 21st day of July, 2014, I served the foregoing REPLY BRIEF OF ROXANE LABORATORIES, INC. IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE A FIRST AMENDED ANSWER and declaration with exhibits in support thereof, by causing a copy of the same to be delivered via email to:

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A handwritten signature in black ink, appearing to read 'Wasim K Bleibel', written over a horizontal line.

Wasim K Bleibel